to EPA, such information should include:

(a) Copies of all of the records relevant to the research specified by §26.1115(a) to be prepared and maintained by an IRB.

(b) Copies of all of the records relevant to the information identified in §26.1125(a) through (f).

(c) Copies of sample records used to document informed consent as specified by §26.1117, but not identifying any subjects of the research.

(d) If any of the information listed in paragraphs (a) through (c) of this section is not provided, the person shall describe the efforts made to obtain the information.

Subpart N [Reserved]

Subpart O—Administrative Actions for Noncompliance

SOURCE: 71 FR 6168, Feb. 6, 2006, unless otherwise noted.

§26.1501 To what does this subpart apply?

This subpart applies to any human research subject to subparts A through L of this part. References to State or local laws in this subpart are intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.

§26.1502 Lesser administrative actions.

(a) If apparent noncompliance with the applicable regulations in subparts A through L of this part concerning the operation of an IRB is observed by an officer or employee of EPA or of any State duly designated by the Administrator during an inspection. EPA may send a letter describing the noncompliance to the IRB and to the parent institution. The agency will require that the IRB or the parent institution respond to this letter within a reasonable time period specified by EPA and describe the corrective actions that will be taken by the IRB, the institution, or both to achieve compliance with these regulations.

(b) On the basis of the IRB's or the institution's response, EPA may schedule a reinspection to confirm the adequacy of corrective actions. In addition, until the IRB or the parent institution takes appropriate corrective action, the Agency may:

(1) Withhold approval of new studies subject to the requirements of this part that are conducted at the institution or reviewed by the IRB;

(2) Direct that no new subjects be added to ongoing studies subject to this part;

(3) Terminate ongoing studies subject to this part when doing so would not endanger the subjects; or

(4) When the apparent noncompliance creates a significant threat to the rights and welfare of human subjects, notify relevant State and Federal regulatory agencies and other parties with a direct interest of the deficiencies in the operation of the IRB.

(c) The parent institution is presumed to be responsible for the operation of an IRB, and EPA will ordinarily direct any administrative action under this subpart against the institution. However, depending on the evidence of responsibility for deficiencies, determined during the investigation, EPA may restrict its administrative actions to the IRB or to a component of the parent institution determined to be responsible for formal designation of the IRB.

§26.1503 Disqualification of an IRB or an institution.

(a) Whenever the IRB or the institution has failed to take adequate steps to correct the noncompliance stated in the letter sent by the Agency under §26.1502(a) and the EPA Administrator determines that this noncompliance may justify the disqualification of the IRB or of the parent institution, the Administrator may institute appropriate proceedings.

(b) The Administrator may disqualify an IRB or the parent institution from studies subject to this part if the Administrator determines that:

(1) The IRB has refused or repeatedly failed to comply with any of the regulations set forth in this part, and

(2) The noncompliance adversely affects the rights or welfare of the human subjects of research.

(c) If the Administrator determines that disqualification is appropriate,